

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



10/533345



(43) International Publication Date
27 May 2004 (27.05.2004)

PCT

(10) International Publication Number
WO 2004/043433 A3

- (51) International Patent Classification⁷: **A61K 9/20**, 31/7072
- (21) International Application Number: PCT/US2003/035830
- (22) International Filing Date: 7 November 2003 (07.11.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/425,182 8 November 2002 (08.11.2002) US
- (71) Applicants (*for all designated States except US*): **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB). **SMITHKLINE BEECHAM CORPORATION** [US/US]; One Franklin Plaza, Philadelphia, PA 19101 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **GOODSON, Gary, Wayne** [US/US]; c/o GlaxoSmithKline, Five Moore Drive, PO Box 13398, Research Triangle Park, NC 27709 (US). **FLOYD, Alison, Green** [US/US]; c/o GlaxoSmithKline, Five Moore Drive, PO Box 13398, Research Triangle Park, NC 27709 (US). **NAVY, Cecilia, Carpenter** [US/US]; c/o GlaxoSmithKline, Five Moore Drive, PO Box 13398, Research Triangle Park, NC 27709 (US).
- (74) Agents: **LEVY, David, J.** et al.; GlaxoSmithKline, Corporate Intellectual Property Department, Five Moore Drive, PO Box 13398, Research Triangle Park, NC 27709 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- (88) Date of publication of the international search report: 29 December 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: PHARMACEUTICAL ANTIVIRAL COMPOSITIONS

(57) Abstract: A pharmaceutical composition comprising 3'-azido-3'-deoxythymidine and (2R,cis)-4-amino-1-(2-hydroxymethyl)-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one suitable for once daily administration.

WO 2004/043433 A3

APR 15 '05 01:30PM CLOXO WELLCOME

Rec'd PCT/PTO 02 MAY 2005

10/533325

P. 1/6

KLP

OCT 20 2004

PATENT COOPERATION TREATY

GLOBAL INTELLECTUAL PROPERTY SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

To:

GLAXOSMITHKLINE
Corp. Intellectual Property Dept.
Attn. Levy, David J.
Five Moore Drive, PO Box 13398
Research Triangle Park
NC 27709
UNITED STATES OF AMERICA

Date of mailing
(day/month/year)

12/10/2004

Applicant's or agent's file reference

PU5025WO/KLP

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US 03/35830

International filing date
(day/month/year)

07/11/2003

Applicant

GLAXO GROUP LIMITED

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90b/s.1 and 90b/s.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Petronella Elsackers

Form PCT/ISA/220 (July 1998)

Express Mail Label No.
EV 332065346 US

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 03/35830

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/20 A61K31/7072

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 681 581 A (J.M.DUNN) 28 October 1997 (1997-10-28) claims examples column 5, line 20 - line 47 column 6, line 1 - column 10, line 20	1-14
A	US 4 917 900 A (H.P.JONES ET AL.) 17 April 1990 (1990-04-17) claims	1-14
A	WO 98/18477 A (GLAXO) 7 May 1998 (1998-05-07) claims	1-14
A	US 6 177 435 B1 (B.A.LARDER ET AL.) 23 January 2001 (2001-01-23) claims examples	1-14

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

S document member of the same patent family

Date of the actual completion of the international search

22 September 2004

Date of mailing of the international search report

12/10/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 cpo nl,
Fax: (+31-70) 340-3016

Authorized officer

Scarponi, U

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/35830**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 14 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/35830

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5681581	A	28-10-1997	AT 186544 T	15-11-1999
			AU 677220 B2	17-04-1997
			AU 4801593 A	03-03-1994
			CA 2141788 A1	17-02-1994
			DE 69327004 D1	16-12-1999
			DE 69327004 T2	29-06-2000
			EP 0654038 A1	24-05-1995
			FI 950439 A	01-02-1995
			NO 950388 A	02-02-1995
			WO 9403471 A1	17-02-1994
US 4917900	A	17-04-1990	AT 63818 T	15-06-1991
			AU 607474 B2	07-03-1991
			AU 1375688 A	29-09-1988
			CA 1308026 C	29-09-1992
			DE 3862974 D1	04-07-1991
			DK 164388 A	28-09-1988
			EP 0284407 A2	28-09-1988
			ES 2033426 T3	16-03-1993
			GR 3002030 T3	30-12-1992
			IE 60605 B1	27-07-1994
			IL 85870 A	16-02-1992
			JP 2719344 B2	25-02-1998
			JP 63255230 A	21-10-1988
			KR 9613434 B1	05-10-1996
			NZ 224026 A	26-03-1991
			PT 87081 A ,B	01-04-1988
			ZA 8802168 A	29-11-1989
WO 9818477	A	07-05-1998	AP 1067 A	01-05-2002
			AT 241364 T	15-06-2003
			AU 736607 B2	02-08-2001
			AU 5314298 A	22-05-1998
			BG 103435 A	28-04-2000
			BR 9712614 A	26-10-1999
			CA 2270174 A1	07-05-1998
			CZ 9901557 A3	13-10-1999
			DE 69722433 D1	03-07-2003
			DE 69722433 T2	08-04-2004
			DK 941100 T3	01-09-2003
			EA 2437 B1	25-04-2002
			EE 9900175 A	15-12-1999
			WO 9818477 A2	07-05-1998
			EP 0941100 A2	15-09-1999
			ES 2200204 T3	01-03-2004
			HK 1020880 A1	28-11-2003
			HR 970569 A1	31-08-1998
			HU 0000344 A2	28-05-2001
			ID 18698 A	30-04-1998
			JP 2001502718 T	27-02-2001
			KR 2000052893 A	25-08-2000
			NO 992091 A	29-06-1999
			NZ 335153 A	27-04-2001
			OA 11038 A	06-02-2002
			PL 333143 A1	22-11-1999
			PT 941100 T	31-10-2003
			SI 941100 T1	31-12-2003
			SK 57599 A3	12-06-2000

Form PCT/ISA/210 (patent family annex) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/35830

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9818477	A	TR 9900950 T2	21-07-1999
		US 6113920 A	05-09-2000
		ZA 9709726 A	29-04-1999
US 6177435	B1 23-01-2001	AT 184787 T	15-10-1999
		DE 69326548 D1	28-10-1999
		DE 69326548 T2	23-03-2000
		DK 639971 T3	20-03-2000
		EP 0639971 A1	01-03-1995
		ES 2138624 T3	16-01-2000
		GR 3031921 T3	31-03-2000
		JP 7109221 A	25-04-1995
		AU 4079593 A	13-12-1993
		WO 9323021 A2	25-11-1993
		JP 2002505657 T	19-02-2002

Form PCT/ISA/210 (patent family annex) (January 2004)